STD Grand Rounds
Presents:
Emergency Contraception

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## Learning Objectives

- Define emergency contraception (EC)
- Identify who would benefit from EC
- Recognize when to use EC
- Discuss appropriate uses of EC
- Describe barriers associated with EC
- Understand the side effects and safety issues of using EC

## Case Presentation

28 year old woman G2P2 delivered 6 weeks ago and presents for postpartum examination. She had sex last night using a condom which broke. She is only breast feeding and does not want to get pregnant. During her pregnancy, she had planned to use oral contraceptives as her regular birth control method.

## Question 1

Is this patient a candidate for emergency contraception?

- Yes
- No

## Question 2

What method of emergency contraception would you use?

- Progestin-only ECPs
- Combined ECPs
- IUD
- Not sure

# Question 3

If the patient is going to use oral contraceptives as her regular birth control method, when should she start?

- Begin after completing her EC
- Start with her next menstrual cycle
- Do not start, instead use a different birth control method
- Not sure

## Unintended Pregnancy

- In USA, about 3 million unintended pregnancies occur each year
- Most result from non-use of contraception or contraceptive failure
- Many could be prevented with the use of emergency contraception

Henshaw SK. Fam Plann Pespect 1998;30:24
Jones RK, et al. Perspect Sex Reprod Health 2002:34;294

## Unintended Pregnancy

- Fertile couple has a 25% chance of pregnancy with repeated unprotected intercourse during a single menstrual cycle
- Single act of unprotected intercourse occurring one to two days prior to ovulation associated with an 8% pregnancy risk
- Pregnancy risk higher in women ages 19-26 years

Wilcox A, et al. NEJM 1995;333:1517
Baird D, et al. Fertil Steril 1999;71:40

## Unintended Pregnancy

- 82% of teen pregnancies
- 56% of pregnancies among women 35-39 years of age
- 77% of pregnancies among women over 40 years of age

Best Intentions, IOM, 1996.

## What is Emergency Contraception?

- EC is defined as a method used to prevent pregnancy after a coital act not adequately protected by a regular method of contraception
- EC does not protect against STD

## Public Health Significance

- STD and unintended pregnancy are related
- Both require sexual contact
- Women suffer the major consequences:
  - STDs are more easily transmitted to women
  - more difficult to diagnose
  - often lead to serious sequale
  - biological burden of unintended pregnancy falls entirely on the woman

Cates et al. Family Planning Perspective 1992.

## Public Health Significance

- Demographics of women most affected by STD and unintended pregnancy are similar:
  - poor,
  - minority women,
  - younger than 25 years old

Upchurch et al. AJPH 1987;77:1427-30

## Potential Impact of Emergency Contraceptive use in U.S. (Annual)

- Potential:
  - Reduce unintended pregnancies: 1.5 million
  - Reduce abortions needed: 0.7 million
- Actual:
  - AGI estimates that 40% of reduction in abortion rate is attributable to EC use

Jones RK, et al. Perspect Sex Reprod Health 2002:34;294

## Why Consider Emergency Contraceptive Use in an STD Clinic?

- We screen sexually active women who are at risk for unintended pregnancy
- We obtain a menstrual history, sexual history and current use of contraception
- Women seen in STD clinics are at high risk for unintended pregnancy

## Profile of Women at Increased Risk of Pregnancy in an STD Clinic

- Study of non-contracepting women in an STD clinic-initiated randomized controlled contraception study
- Study assessed predictors of pregnancy
- 673 women had follow-up information; 220 incident pregnancies occurred within 1 year

Shlay et al. Sex Transm Dis 2002;29:491-6

## Profile of Women at Increased Risk of Pregnancy in an STD Clinic

- Combined demographic and behavioral characteristics correlated with incident pregnancy included 9 variables:
  - age $\leq$ 19
  - being non-Caucasian
  - having $\leq$ to a high school diploma or a general equivalency diploma (GED)
  - having had at least one previous pregnancy

## Profile of Women at Increased Risk of Pregnancy in an STD Clinic

- having not used any birth control method with last sexual encounter
- having had sex at least once a week for the past 4 months
- having had a previous abortion
- $\geq$3 sex partners within the past month
- being <17 years of age at the time of the first pregnancy

## Profile of Women at Increased Risk of Pregnancy in an STD Clinic

- 27% had ≥6 characteristics
- Cumulative risk of pregnancy for women with ≥6 characteristics was 51% compared with 26% for women with ≤5 characteristics
- Easy to perform the risk assessment in a clinical setting
- Able to provide a targeted intervention for a higher risk group

## Fertile Period

- Risk of pregnancy greatest during fertile period:
  - –4-5 days before ovulation until the day after ovulation

## Emergency Contraception Options

- Combined estrogen-progestin regimen
- Progestin-only regimen
- Copper intrauterine device
- Anti-progesterone (mifepristone): not available in U.S.

## Potential Indications for Use of Emergency Contraception

- Lack of contraceptive use during coitus
- Mechanical failure of male condom
- Failure of spermicide tablet/film to melt during intercourse
- Error in practicing withdrawal
- Missed combined OCs or progestin only OCs

## Potential Indications for Use of Emergency Contraception

- Expulsion of IUD
- Exposure to potential teratogen while not using effective contraception
- Late injection of injectable contraceptive
- Sexual assault

## Combined Emergency Contraceptive Pills

- Dedicated product (Preven) containing ethinyl estradiol (EE) and levonorgestrel (LNG)
- Ordinary OCs containing EE and LNG/norestrel (NG)
  - 2 doses of 2, 4, or 5 pills, depending on brand
- First dose within 72 hours after unprotected intercourse, second does 12 hours later
- Side effects: nausea (50%) and vomiting (20%)
- Reduces the risk of pregnancy by 75%

## Progestin-Only Emergency Contraceptive Pills

- Dedicated product (Plan B) containing only LNG, 1 tablet/dose
- Birth control pills containing only NG, 20 tablets/dose
- First dose within 72 hours after unprotected intercourse, second does 12 hours later
- More effective than combined ECPs
- Less nausea and vomiting than combined ECPs
- Reduces the risk of pregnancy by 88%

## Thirteen Brands Available in U.S.

| Brand | Pills/Dose | E.E./Dose (ug) | Levo/Dose (mg) |
|---|---|---|---|
| Ovral | 2 white pills | 100 | 0.50* |
| Alesse | 5 pink pills | 100 | 0.50 |
| Levlite | 5 pink pills | 100 | 0.50 |
| Nordette | 4 light orange pills | 120 | 0.60 |
| Levlen | 4 light orange pills | 120 | 0.60 |
| Lo/Ovral | 4 white pills | 120 | 0.60* |
| Triphasil | 4 yellow pills | 120 | 0.50 |
| Tri-Levlen | 4 yellow pills | 120 | 0.50 |
| Trivora | 4 pink pills | 120 | 0.50 |
| Ovrette | 20 yellow pills | 0 | 0.75* |
| Preven | 2 blue pills | 50 | 0.25 |
| Plan B | 1 white pill | 0 | 0.75 |

* denotes pills containing norgestrel

## Progestin-Only Emergency Contraception

Single Dose versus 2 Doses

| Regimen | 2 Doses 0.75 mg | 1 Dose 1.5 mg |
|---|---|---|
| Pregnancies | 7/560 | 4/600 |
| Effectiveness | 86.8% | 92.9% |
| Headaches | 14.5% | 21.3% |
| Breast tenderness | 8.8% | 12.9% |

No differences seen in nausea, vomiting, dizziness, lower abdominal pain or heavy menses

Arowojolu AO, et al. Contraception 2002;66:269-73

## Progestin-Only Emergency Contraception

Single Dose versus 2-Dose Regimens within 120 hours of exposure

| | Pregnancies | Absolute #s |
|---|---|---|
| Single 10mg Mifepristrone | 1.5% | 21/1359 |
| 2 dose LNG (0.75mg) | 1.8% | 24/1356 |
| 1 dose LNG (1.5mg) | 1.5% | 20/1356 |

•No differences in side effects
•Usually menstruate within 2 days of expected date

Von Hurtzen W, et al. Lancet 2002;360:1803-10

## Copper IUD Insertion

- Copper-T IUD (ParaGard)
- Insertion within 5 days after unprotected intercourse
- Appropriate for women who meet the screening criteria for regular use
- 10 more years of highly effective contraception
- Reduces the risk of pregnancy by 99.9%

## Emergency Contraceptive Effectiveness

If 1000 women have unprotected sex once in the second or third week of their cycle

- 80 (8%) will become pregnant without treatment
- 20 (2%) will become pregnant following use of combined ECPs (75% reduction)
- 10 (1%) will become pregnant following use of progestin-only ECPs (an 88% reduction)
- 1 (0.1%) will become pregnant following emergency IUD insertion (99.9% reduction)

## Mechanism of Action

- Prevents a pregnancy from starting; does not interrupt an early established pregnancy
- Mechanism of action not well studied, so not well understood
- Presumed action:
  - Multiple mechanisms that depend on the timing of their administration in the menstrual cycle

## Mechanism of Action

- When taken before ovulation, ECPs inhibit ovulation
- Additional mechanisms:
  - Changes in cervical mucus and the endometrium
  - Alterations in transport of sperm, egg or embryo in reproductive tract
  - Interference with corpus luteum function
  - Direct inhibition of fertilization

## Mechanism of Action

- Many patients confuse emergency contraception with medical abortion, since both occur after intercourse
- 6-7 days elapse between a coital act and establishment of a pregnancy which is defined as implantation
- Emergency contraception acts in this interval to prevent pregnancy
- ECPs cannot interrupt an established pregnancy

## Safety of Emergency Contraception

- Hormonal contraception is very safe
- No deaths have been linked to EC
- Few case reports of serious adverse events among users does not support a causal association
- Overdose is not lethal; no additive potential
- Hormonal contraception is safer than aspirin

## Medical Contraindications

- No contradictions to hormonal ECP exist
- Method not indicated for a woman with a suspected or confirmed pregnancy; no harm if given
- FDA-approved package inserts for combined and progestin-only products list several precautions; derived for combined OCs

## Medical Contraindications

- Clinicians may prefer progestin-only ECP for women with classic contraindications to estrogen (e.g., focal migraine, hormone dependent tumors, idiopathic thrombosis). Need to look at risk benefit ratio

## Medical Contraindications

- WHO guidelines:
  - No restrictions if breast feeding or history of ectopic pregnancy
  - Benefit outweighs risk
    - History of severe cardiovascular disease
    - Angina pectoris
    - Migraine
    - Severe liver disease
- Neither smoking nor age is a contraindication

WHO 2000: Improving access to quality care in family planning

## Drug Interactions with ECP

- One case report of increase INR after taking LNG ECP by woman taking warfarin
- No other data available on interactions between ECP and other drugs
- Evidence indicates rifampin, some anticonvulsant drugs and St. John's wort may decrease efficacy of OCs; consider increasing dose
- No effect with antibiotics

## Laboratory Testing

- For hormonal ECP, assessment requires only a history; exam and lab work are not necessary
- Pregnancy based on patient's menstrual history; if pregnancy is suspected, confirm with pregnancy testing
- Routine pregnancy testing not indicated
- Standard pretreatment assessment for IUD is required

## Side Effects

- Nausea and Vomiting more common with combined ECP compared to progestin-only ECP
- Pretreatment with antiemetic drug meclizine significantly reduces nausea and vomiting
- Irregular vaginal bleeding; dizziness, headache, breast tenderness, lower abdominal pain

## Follow-Up Management

- Routine follow-up is unnecessary
- If menses has not returned within 1 week after expected time (or within 4 weeks after ECP), pregnancy testing is indicated
- Further counseling needed for long-term contraception

## Repeated Use of Emergency Contraception

- ECP is not intended for frequent use
- Less effective and more side effects than other methods
- Study of high-dose LNG used for recurring postcoital contraception found likelihood of harm due to repeated use is low
- Need to address issues with current contraceptive method

## Initiation of Other Contraceptive Method

- Timing of initiation of other method varies
- OCs: begin after complete ECP or with next menses
- Injectables: delay until next menses

## Initiation of Other Contraceptive Method

- IUD: insert with next cycle, unless used for emergency contraception
- If uses condoms, consider advance provision of ECP
- Interim method required till initiation of long-term method

## Medicolegal Risks

- Risk of litigation associated with provision of ECP is negligible
- ACOG Practice Bulletin Number 25 (March 2001) established the professional standard of care
- Lawsuits won against providers who failed to offer emergency contraception
  - Brownfield vs. Daniel Freeman Marina Hospital

## Barriers to Widespread Use of Emergency Contraception

- Until recently, no dedicated products for emergency contraception
- Lack of commercial marketing and cost issues
- Requirement for prescription by a provider
- Lack of use of advance prescribing
- Off-label use of regular OCs still common
- Concerns about risky behavior
- Abandonment of regular contraception
- Attitudes toward sexuality

## Direct Access to Emergency Contraception

- Randomized trial to evaluate the effect of direct access to EC through pharmacies and advanced provision vs. clinic access on use of EC, pregnancy rate and new STI
- Advanced access group (37.4%) almost twice as likely to use EC as clinic access group (21.0%)
- Pharmacy access (24.2%) did not increase use relative to clinic access (21.0%)
- Rates of unprotected intercourse, pregnancy and new STIs were similar across groups

Raine T, et al. JAMA 2005;293:54-62.

## Survey of Experience with Emergency Contraception

- Obstetricians/gynecologists (2001)
  - Only 25% routinely discussed emergency contraception with patients
  - 80% prescribed in last year (61% $\leq$5 times)
- Family physicians (2001)
  - Only 14% routinely discussed emergency contraception with patients
  - 36% prescribed in last year (83% $\leq$5 times)

Kaiser Family Foundation, 2003

## Survey of Experience with Emergency Contraception

- Women ages 18-44 years (2003)
  - Only 6% ever used ECPs
  - 68% knew about something to prevent pregnancy if used in the next few days after unprotected sex

Kaiser Family Foundation, 2003

## The Solutions

- Change provider practices
  - Routinely counsel and educate women (and men)
  - Provide ECPs in advance of need
- Market emergency contraception
  - Marketing promotes awareness
  - Dedicated EC product are less confusing to users and providers, and may reduce the chances of incorrect prescribing or use
- Change from Rx to over/behind the counter after public educated

## Politics of Emergency Contraception

- While 2 FDA advisory committees recommended approval of OTC availability of Plan B, approval was rejected by FDA in May 2004
  - Safety of adolescents under 16 years without supervision
- FDA decision-making process potentially influenced by political considerations, undermining integrity of the decision-making process

## Action Steps for Providers

- Ensure all staff know that you provide emergency contraceptives
- Routinely discuss emergency contraception with patients
- Do not require a pelvic prior to prescribing ECPs
- Prescribe ECPs by telephone

## Action Steps for Providers

- Provide ECPs in advance
- Discuss anti-nausea medicines with clients
- Extend the 72-hour window when prescribing ECPs
- Advertise the availability of emergency contraception in your clinic

## Cost-Effectiveness

- ECPs reduces expenditures on medical care by reducing unintended pregnancies
- Insertion of IUD is only cost saving if used for ongoing contraception
- Emergency contraception results in social cost savings by reducing the psychological costs of unintended pregnancy

## Conclusion

- Approximately half of all women aged 15-44 in US have experienced at least one unintended pregnancy
- Emergency contraception is effective, safe and simple to use
- Improving availability of emergency contraception reduces unintended pregnancy and the consequent need for abortion

For further information and resources about EMERGENCY CONTRACEPTION go to:

**www.BackUpYourBirthControl.org**

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**WWW.STDCentral.org**